

Atty. Dkt. No. 029849-0203



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Vaillant and Juteau

Title:

**ANTIVIRAL** 

OLIGONUCLEOTIDES

TARGETING HIV

Appl. No.:

10/661,091

Filing Date:

09/12/2003

Examiner:

Art Unit:

1614

## **CERTIFICATE OF MAILING**

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INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Mail Stop Amendment-IDS Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

I The USPTO has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statements in a patent application filed after June 30, 2003 and in an international application that has entered the national stage under 37 USC §371 after June 30, 2003. Accordingly, copies of these types of documents are not being supplied in connection with this application. Reference is being made to OG Notice dated August 5, 2003, *Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003*.

Applicants submit herewith on Form PTO/SB/08 a listing of the documents cited by or submitted to the U.S. PTO in related application Serial No. 10/661,403, also filed 09/12/2003. As provided in 37 CFR §1.98(d), copies of the documents are not being provided since they were

previously submitted to the United States Patent & Trademark Office in that application and are on file with the USPTO.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

## TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

## RELEVANCE OF EACH DOCUMENT

The relevance of the foreign-language document is explained in the related application.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even

entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872.

Respectfully submitted,

Date November 23, 2004

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David P. Lentini

Attorney for Applicant Registration No. 33,944

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Substitute for form 1449 Complete if Known INFORMATION DISCLOSURE **Application Number** 10/661,099 STATEMENT BY APPLICANT Filing Date 09/12/2003 **First Named Inventor** Andrew Vaillant Group Art Unit 1614 (use as many sheets as necessary) Examiner Name

	U.S. PATENT DOCUMENTS							
		U.S. Patent	Document		Date of Publication of	Pages, Columns, Lines,		
Examiner Initials*	Cite No. <sup>1</sup>	Number	Kind Code <sup>2</sup> (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Where Relevant Passages or Relevant Figures Appear		
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Attorney Docket Number

FOREIGN PATENT DOCUMENTS								
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	A1	WO	93/24510					

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	А3	ALLEN and CHONN, "Large Unilamellar Liposomes with Low Uptake into the Reticuloendothelial System," FEBS Letters 223(1):42-46 (1987)	
	A4	ARCHAMBAULT, et al., "Phosphorothioate oligonucleotides inhibit the replication of lentiviruses and type D retroviruses, but not that of type C retroviruses," Arch Virol 139:97-109 (1994)	

Examiner Signature	Date Considered	

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A5	BERKOW, et al., "Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)," The Merck Manual of Diagnosis and Therapy, 15 <sup>th</sup> ed., 2499-2506 and 46-49 (1987)	
A6	BLUME and CEVC, "Liposomes for the sustained drug release in vivo," <i>Biochimica et Biophysica Acta</i> 1029:91-97 (1990)	
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	A5 A6 A7 A8 A9 A10 A11	Cite No. Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.  A5 BERKOW, et al., "Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)," The Merck Manual of Diagnosis and Therapy, 15 <sup>th</sup> ed., 2499-2506 and 46-49 (1987)  A6 BLUME and CEVC, "Liposomes for the sustained drug release in vivo," Biochimica et Biophysica Acta 1029:91-97 (1990)  A7 BRUNTON, "Section VI Drugs Affecting Gastrointestinal Function," The Pharmacological Basis of Therapeutics 9(38):934-935 (1996)  A8 BUUR, et al., "Penetration of 5-Fluorouracil and Prodrugs Across the Intestine of the Albino Rabbit: Evidence for Shift in Absorption Site from the Upper to the Lower Region of the Gastrointestinal Tract by Prodrugs," Journ. of Controlled Release 14:43-51 (1990)  A9 CAMPBELL and REIN, "In Vitro Assembly Properties of Human Immunodeficiency Virus Type 1 Gag Protein Lacking the p6 Domain," Journ. of Virol. 73:2270-2279 (1999)  A10 CEVC, et al., "Ultraflexible vesicles, Transfersomes, have an extremely low pore penetration resistance and transport therapeutic amounts of insulin across the intact mammalian skin," Biochimica et Biophysica Acta 1368:201-215 (1998)  A11 CHENG, et al., "Interactions Between Single-Stranded DNA Binding Protein and Oligonucleotide Analogs with Different Backbone Chemistries," Journ. Mol. Recognition 10:101-107 (1997)  A12 CONSTANTINIDES, et al., "Formulation and Intestinal Absorption Enhancement Evaluation of Water-in-Oil Microemulsions Incorporating Medium-Chain Glycerides," Pharmaceutical Res. 11:1385-1390 (1994)  A13 CROOKE, et al., "Pharmacokinetic Properties of Several Novel Oligonucleotide Analogs in mice," Journ. Pharm. and Experim. Therap. 277(2):923-937 (1996)

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	STATEMEN'	T BY APPLI	CANT	Filing Date	09/12/2003	-
				First Named Inventor	Andrew Vaillant	
				Group Art Unit	1614	
(use as many sheets as necessary)				Examiner Name		
Sheet	3	of	13	Attorney Docket Number	029849-0203	

		NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.					
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	A48	MATSUKURA et al., "Antisense phosphorothioates as antivirals against human immunodeficiency virus (HIV) and hepatitis B virus (HBV)." Toxicology Letters, 82/83: 435-538, 1995.	
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	INFORMATI	ON DISCLO	SURE	Application Number	10/661,099	
	STATEMEN'	T BY APPLI	CANT	Filing Date	09/12/2003	
				First Named Inventor	Andrew Vaillant	
				Group Art Unit	1614	
(use as many sheets as necessary)				Examiner Name		
Sheet 8 of 13			13	Attorney Docket Number	029849-0203	

	NON PATENT LITERATURE DOCUMENTS	
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A56	NANDI, et al., "DNA-induced Partial Unfolding of Prion Protein Leads to its Polymerisation to Amyloid," <i>J. Mol. Biol.</i> 322:153-161 (2002)	
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A58	OBERHAUSER and WAGNER, "Effective incorporation of 2'-0-methyl-oligoribonucleotides into liposomes and enhanced cell association through modification with thiocholesterol," <i>Nucleic Acids Res.</i> 20(3):533-538 (1992)	
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A60	ORUM and WENGEL, "Locked nucleic acids: A promising molecular family for gene-function analysis and antisense drug development," <i>Curr. Op. in Molecular Ther.</i> 3:239-243 (2001)	
A61	PAN et al., "Isolation of virus-neutralizing RNAs from a large pool of random sequences." Proc. Nat. Acad. Sci. USA, 92:11509-11513, 195.	
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	A55 A56 A57 A58 A60	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.  A55  MURANISHI, S., "Absorption Enhancers," Crit. Rev. in Ther. Drug Carr. Syst. 7:1-33 (1990)  A56  NANDI, et al., "DNA-induced Partial Unfolding of Prion Protein Leads to its Polymerisation to Amyloid," J. Mol. Biol. 322:153-161 (2002)  A57  NEURATH, et al., "Anti-HIV-1 activity of anionic polymers: a comparative study of candidate microbicides," BMC Infectious Diseases 2:1-11 (2002)  A58  OBERHAUSER and WAGNER, "Effective incorporation of 2-0-methyl-oligoribonucleotides into liposomes and enhanced cell association through modification with thiocholesterol," Nucleic Acids Res. 20(3):533-538 (1992)  A59  OLIVIERI, et al., "Hepatitis C Virus and Arthritis," Rheumatic Diseases Clinics of North America 29:1-18 (2003)  A60  ORUM and WENGEL, "Locked nucleic acids: A promising molecular family for gene-function analysis and antisense drug development," Curr. Op. in Molecular Ther. 3:239-243 (2001)  A61  PAN et al., "Isolation of virus-neutralizing RNAs from a large pool of random sequences." Proc. Nat. Acad. Sci. USA, 92:11509-11513, 195.

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	INFORMATION D	DISCLO	SURE	Application Number	10/661,099	
	STATEMENT BY	<b>APPLI</b>	CANT	Filing Date	09/12/2003	
				First Named Inventor	Andrew Vaillant	
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		A96	International Search Report from PCT Application No. PCT/IB03/04573 dated Feb. 18, 2004.					

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